# E-ROC

## Ethical Research Oversight Course

User Guide
October 2013

# www.primrelearning.com

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Available courses
E-ROC: Ethical Research Oversight Course
E-ROC
E-ROC: Ethical Research Oversight Course (formerly the Ethical Oversight of Human Subjects Research online course), is a four and a half hour, online course that presents an in-depth exploration of the function and purpose of institutional review boards (IRBs) through an interactive, realistic interface. The course addresses the roles of IRB members who tackle the challenging, ethical, and regulatory issues of human subjects research.
You are not logged in. (Login)

Go to www.primrelearning.com and click on Login.

# Logging In

Your username is your email address, and your temporary password is Pwtemp00! Once you type in both your username and password, click the red login button.

# Logging In

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You are logged in as [redacted] Logout)
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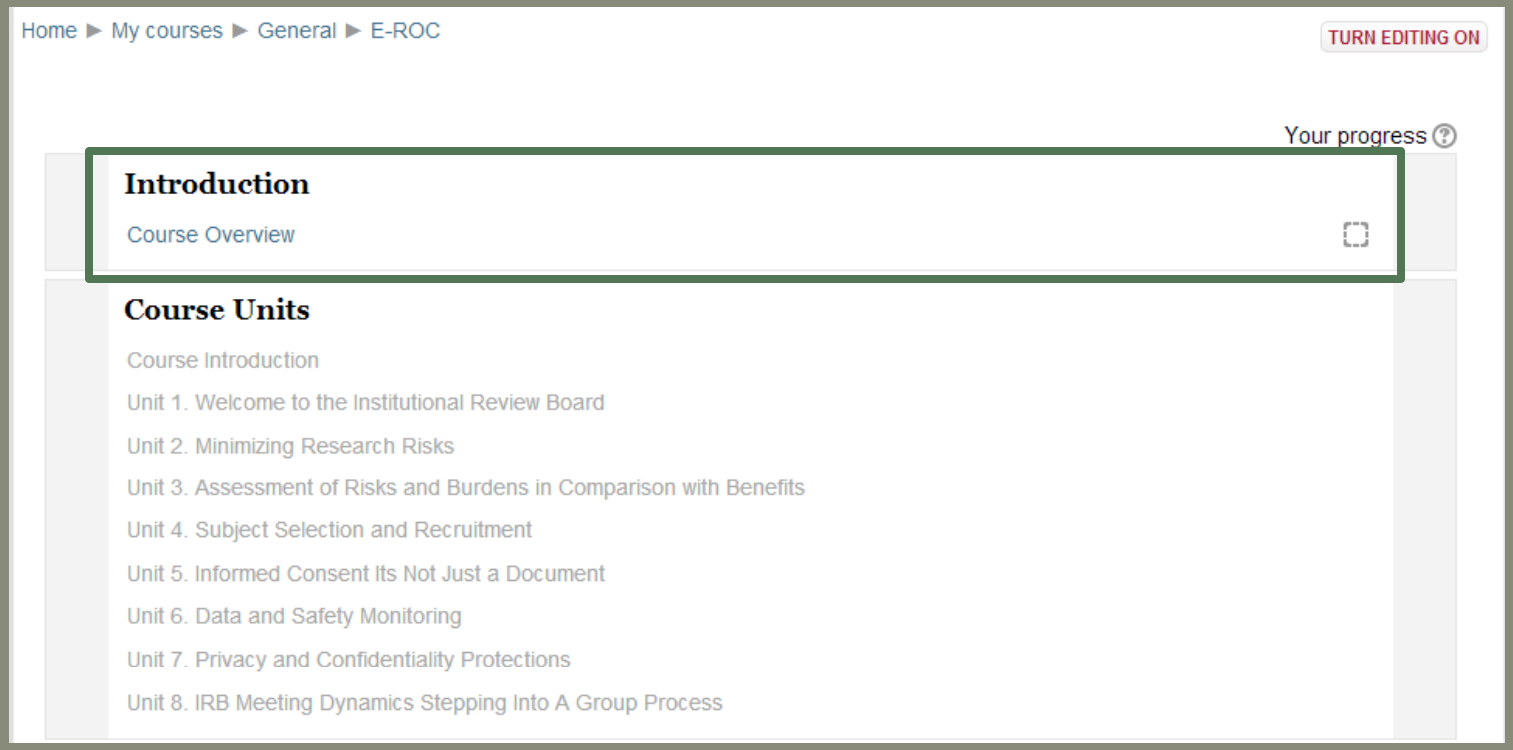
You are logged in as [redacted] (Logout)

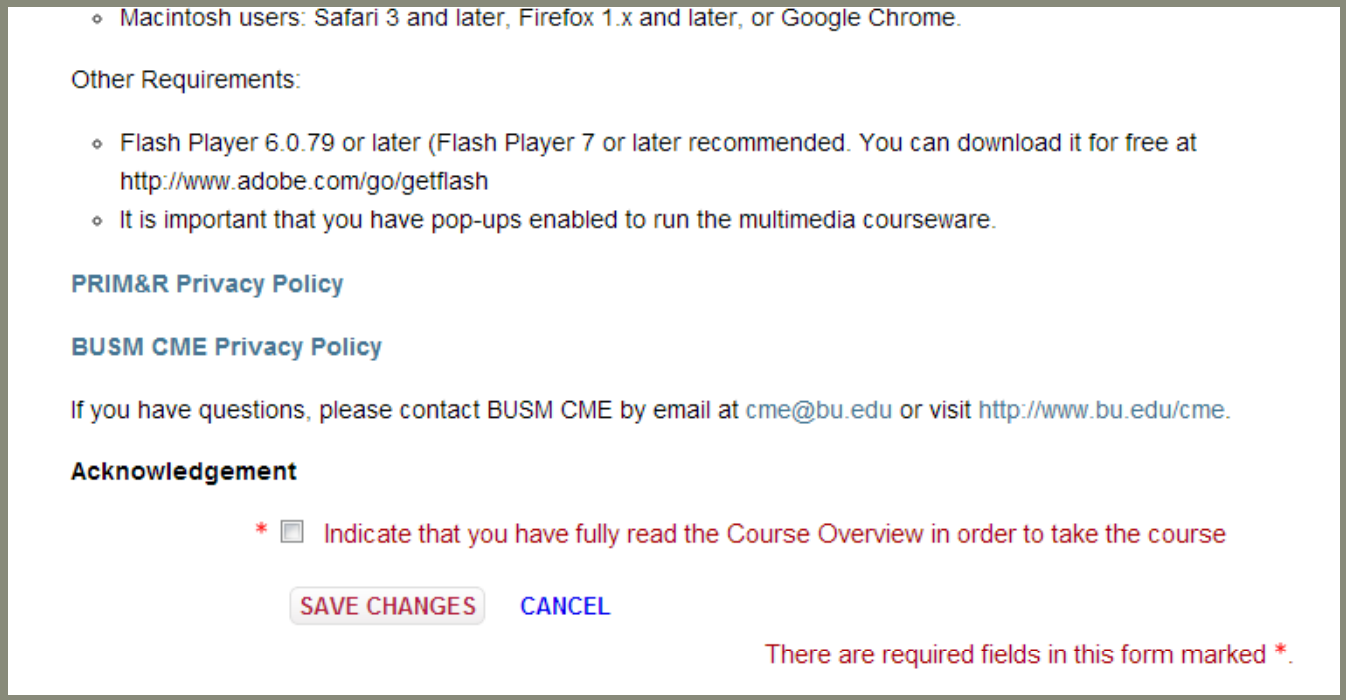
Click on the blue hyperlink for
E-ROC: Ethical Research Oversight Course

# Course Overview Form


Home ▶ My courses ▶ General ▶ E-ROC
TURN EDITING ON
Your progress
Introduction
Course Overview
Course Units
Course Introduction
Unit 1. Welcome to the Institutional Review Board
Unit 2. Minimizing Research Risks
Unit 3. Assessment of Risks and Burdens in Comparison with Benefits
Unit 4. Subject Selection and Recruitment
Unit 5. Informed Consent Its Not Just a Document
Unit 6. Data and Safety Monitoring
Unit 7. Privacy and Confidentiality Protections
Unit 8. IRB Meeting Dynamics Stepping Into A Group Process

In order to access the content of the course, you must first read the Course Overview. This only has to be done once.

# Course Overview Form



- Macintosh users: Safari 3 and later, Firefox 1.x and later, or Google Chrome.

Other Requirements:

- Flash Player 6.0.79 or later (Flash Player 7 or later recommended. You can download it for free at http://www.adobe.com/go/getflash
- It is important that you have pop-ups enabled to run the multimedia courseware.

**PRIM&R Privacy Policy**

**BUSM CME Privacy Policy**

If you have questions, please contact BUSM CME by email at cme@bu.edu or visit http://www.bu.edu/cme.

**Acknowledgement**

* ☐ Indicate that you have fully read the Course Overview in order to take the course

SAVE CHANGES CANCEL

There are required fields in this form marked *.

Please read the disclosure documents. When you scroll to the bottom of the screen, you must mark that you have fully read the Course Overview Form. Then, please click save changes.

# Course Overview Form

PRIM&R's Online Learning Center
Home ► My courses ► General ► E-ROC ► Introduction ► Course Overview
Course
E-ROC: Ethical Research Oversight Course
Course Overview
Jointly sponsored by
PRIM&R
PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH
BOSTON UNIVERSITY
You indicated that you have fully read the Course Overview. Click here to access the Course.
This Continuing Medical Education (CME) activity, E-ROC: Ethical Research Oversight Course (formerly the Ethical Oversight of Human Subjects Research online course), is a four and a half hour, online course that presents an in-depth exploration of the function and purpose of institutional review boards (IRBs) through an interactive, realistic interface. The course involves watching and listening to eight course modules and then completing a test that will assess your comprehension of the information presented. To successfully complete this CME activity, clinicians are required to complete the entire course, submit the post-test, achieve a score of 80% or better, and complete a course evaluation.

You will then be brought back to the top of the page. Click on the blue click here hyperlink to the table of contents/course menu.

# Access to Modules

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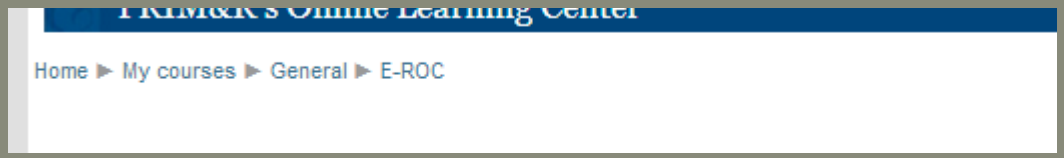
Course Units
Course Introduction
Unit 1. Welcome to the Institutional Review Board
Unit 2. Minimizing Research Risks
Unit 3. Assessment of Risks and Burdens in Comparison with Benefits
Unit 4. Subject Selection and Recruitment
Unit 5. Informed Consent Its Not Just a Document
Unit 6. Data and Safety Monitoring
Unit 7. Privacy and Confidentiality Protections
Unit 8. IRB Meeting Dynamics Stepping Into A Group Process
Course Wrap Up
Course Assessment
Course Feedback Survey

You are now brought back to the course menu/table of contents. You will notice that all of your data has transferred from the previous learning management system.

# Changing Your Password

First, click on the My Courses breadcrumb:




In the Settings block, click on My profile settings, and then click Change password:

# Navigating the Course

PRIM&R's Online Learning Center
Home ▶ My courses ▶ General ▶ E-ROC
TURN EDITING ON
Your progress
Introduction
Course Overview
Course Units
Course Introduction
Unit 1. Welcome to the Institutional Review Board
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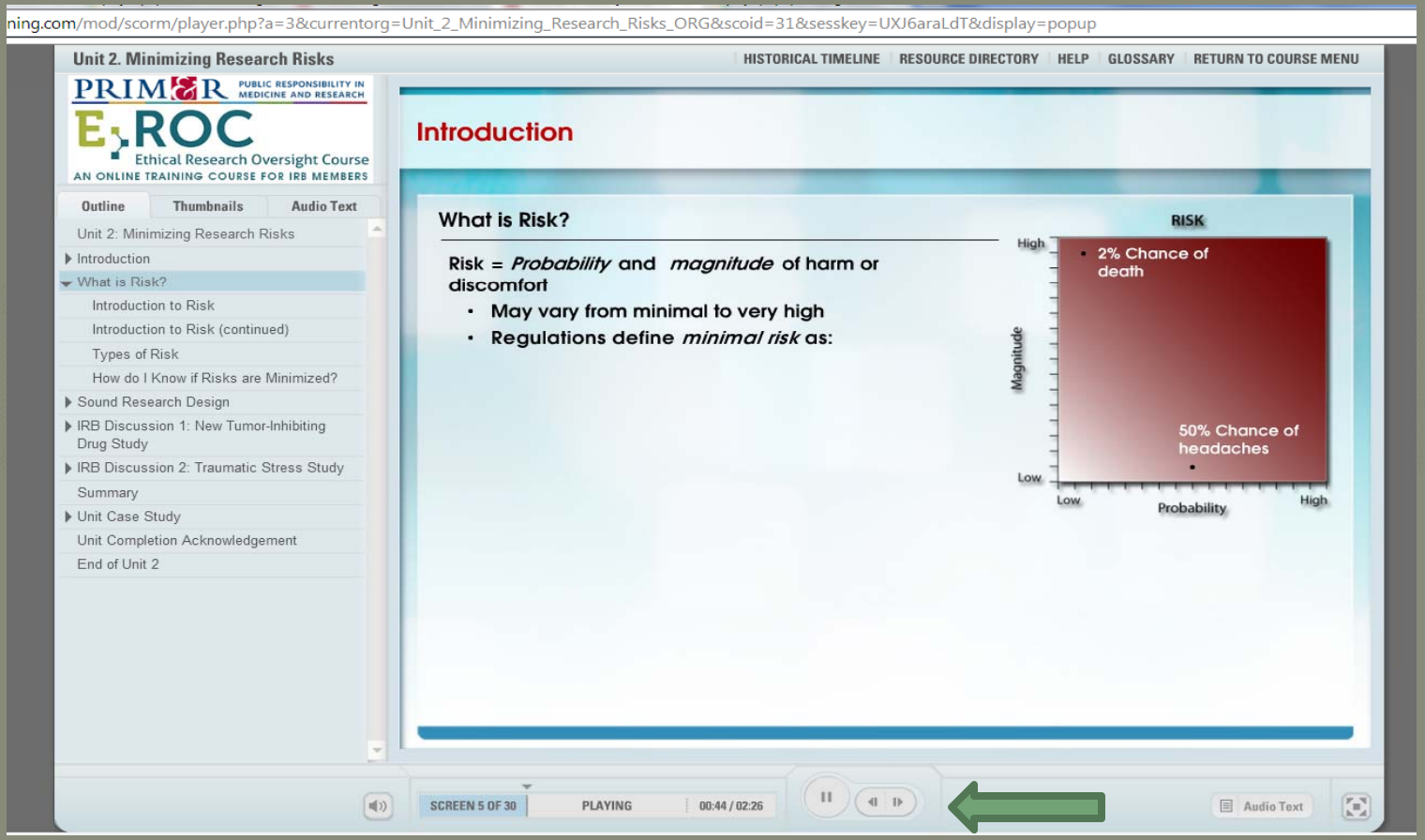
Course Wrap Up
Course Assessment
Course Feedback Survey

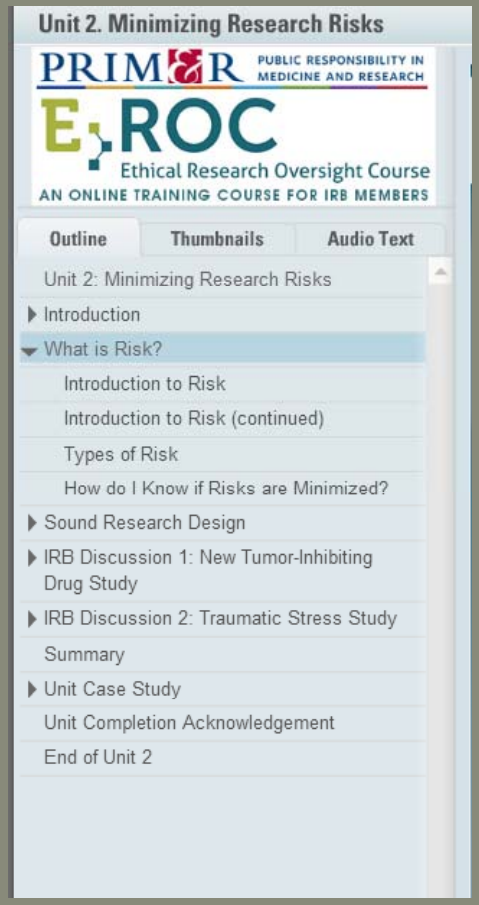
From the course menu/table of contents, you will notice that all of your data has transferred from the previous learning management system.

# Modules



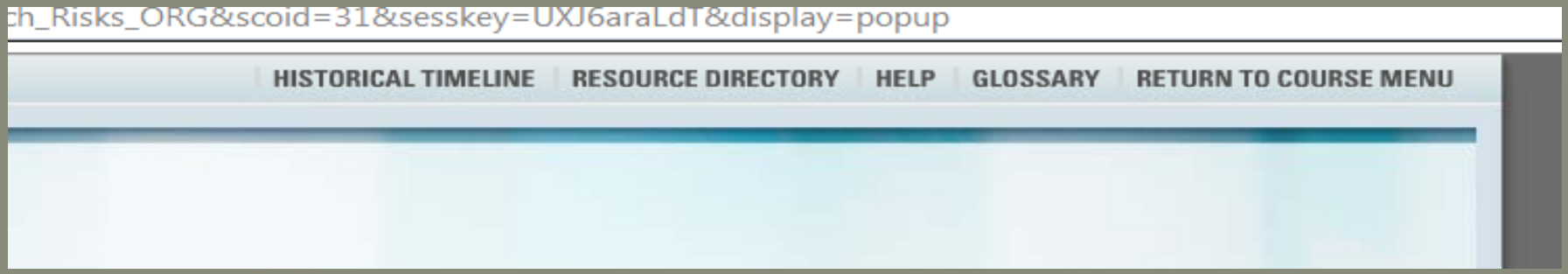

Each module is narrated, and can be stopped or paused at any time using the controls at the bottom of the screen.

# Left Screen Toolbar



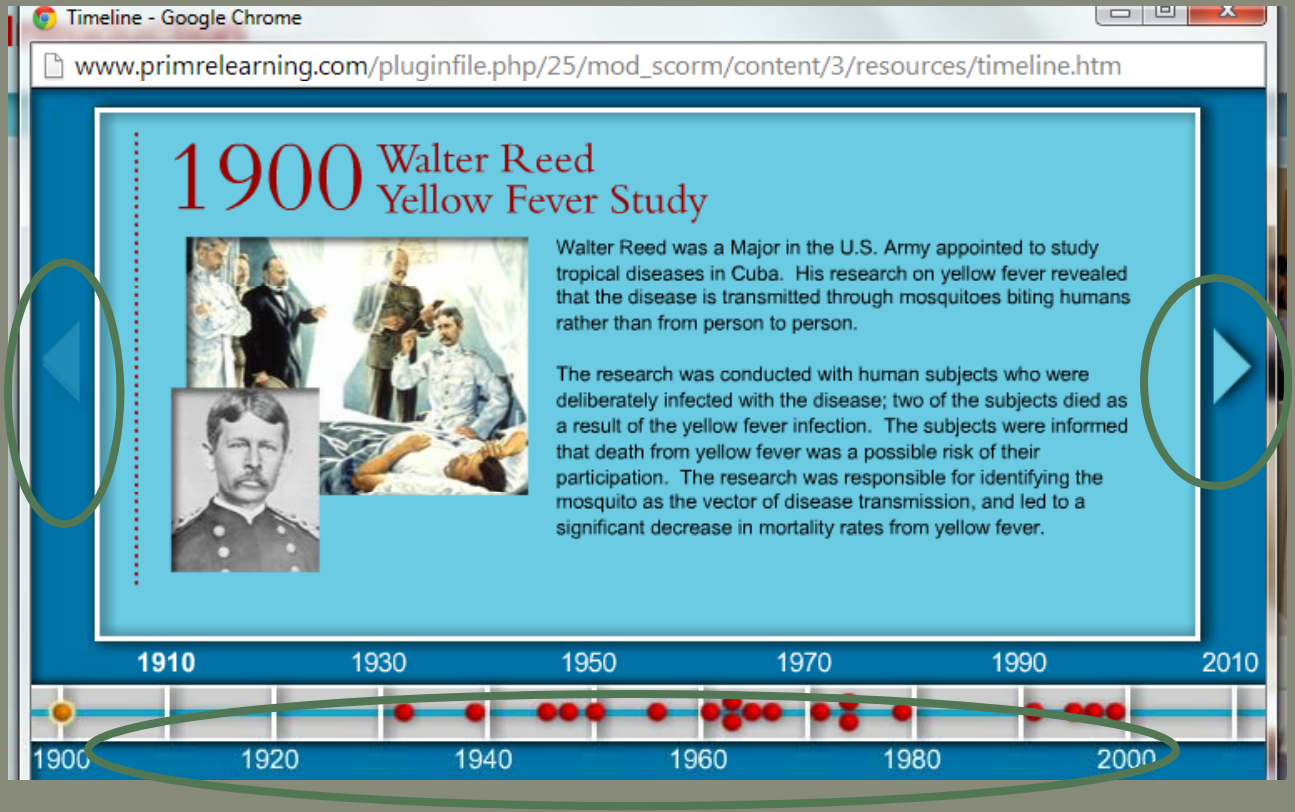

- The Outline screen acts as a table of contents for the unit.
- The Thumbnails screen previews each slide.
- The Audio Text screen transcribes what the narrator is saying.

# Top Screen Toolbar



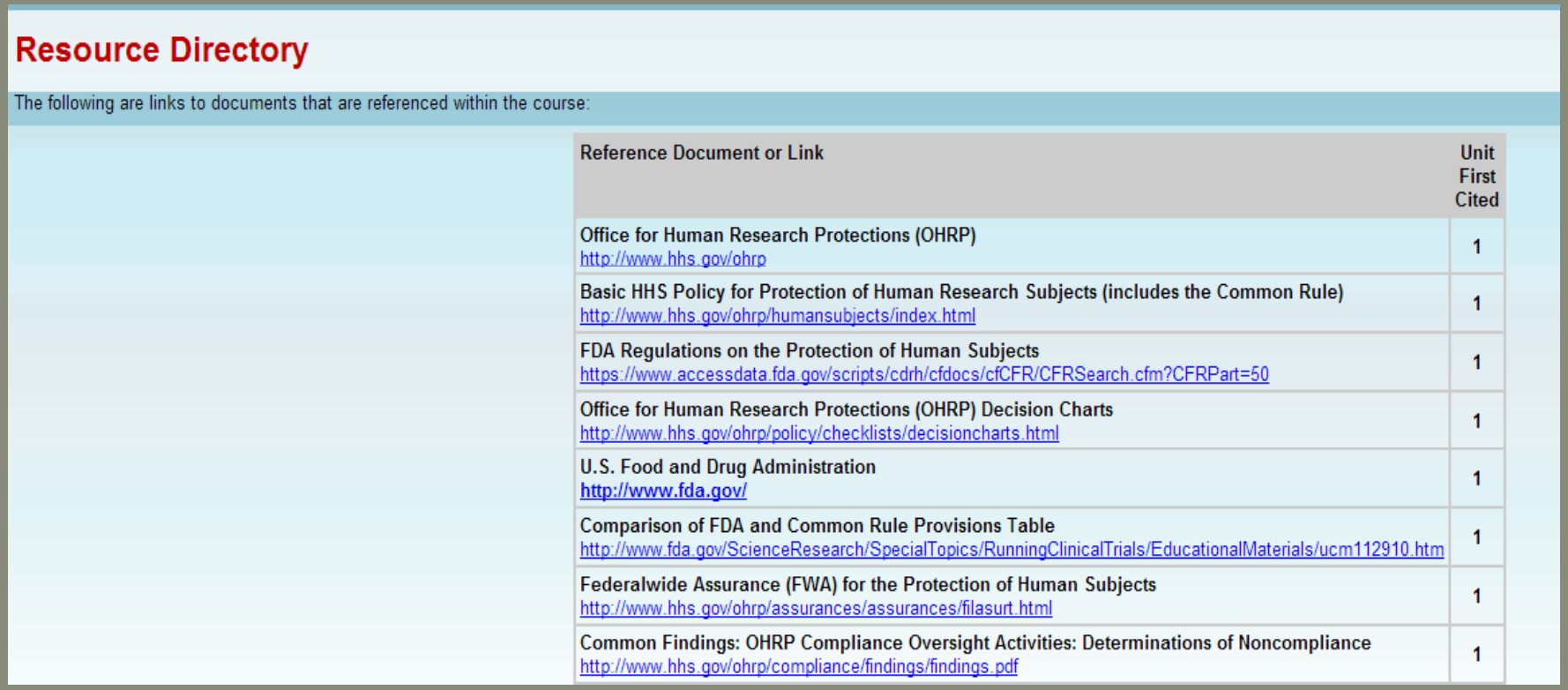

- The Historical Timeline, Resource Directory, Help, Glossary and Return to Course Menu links appear at the top of each unit.

# Historical Timeline


Timeline - Google Chrome
www.primrelearning.com/pluginfile.php/25/mod_scorm/content/3/resources/timeline.htm
1900 Walter Reed Yellow Fever Study
Walter Reed was a Major in the U.S. Army appointed to study tropical diseases in Cuba. His research on yellow fever revealed that the disease is transmitted through mosquitoes biting humans rather than from person to person.
The research was conducted with human subjects who were deliberately infected with the disease; two of the subjects died as a result of the yellow fever infection. The subjects were informed that death from yellow fever was a possible risk of their participation. The research was responsible for identifying the mosquito as the vector of disease transmission, and led to a significant decrease in mortality rates from yellow fever.
1910 1930 1950 1970 1990 2010
1900 1920 1940 1960 1980 2000

The historical timeline details important events in the history of research ethics, dating back to 1900. You can navigate using the arrows on the side of each slide, or you can click on the red dots that appear at the bottom of the screen.

# Resource Directory



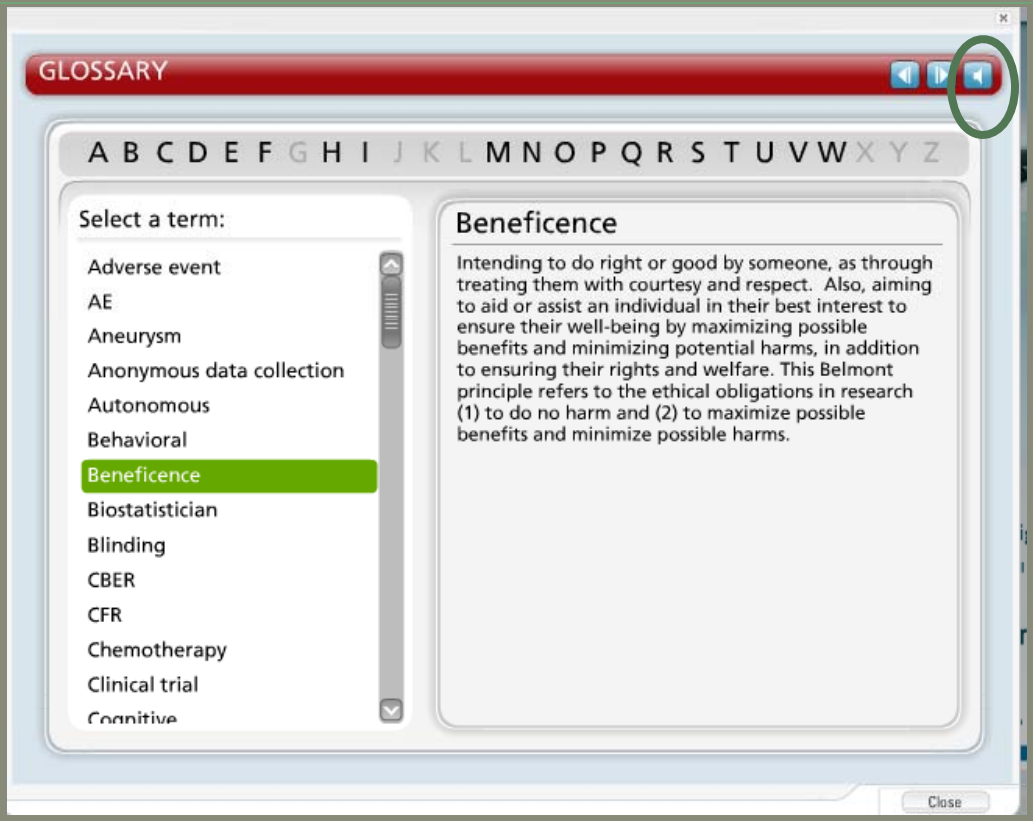
## Resource Directory

The following are links to documents that are referenced within the course:

| Reference Document or Link | Unit First Cited |
|---|---|
| Office for Human Research Protections (OHRP)<br>http://www.hhs.gov/ohrp | 1 |
| Basic HHS Policy for Protection of Human Research Subjects (includes the Common Rule)<br>http://www.hhs.gov/ohrp/humansubjects/index.html | 1 |
| FDA Regulations on the Protection of Human Subjects<br>https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=50 | 1 |
| Office for Human Research Protections (OHRP) Decision Charts<br>http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html | 1 |
| U.S. Food and Drug Administration<br>http://www.fda.gov/ | 1 |
| Comparison of FDA and Common Rule Provisions Table<br>http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/EducationalMaterials/ucm112910.htm | 1 |
| Federalwide Assurance (FWA) for the Protection of Human Subjects<br>http://www.hhs.gov/ohrp/assurances/assurances/filasurt.html | 1 |
| Common Findings: OHRP Compliance Oversight Activities: Determinations of Noncompliance<br>http://www.hhs.gov/ohrp/compliance/findings/findings.pdf | 1 |

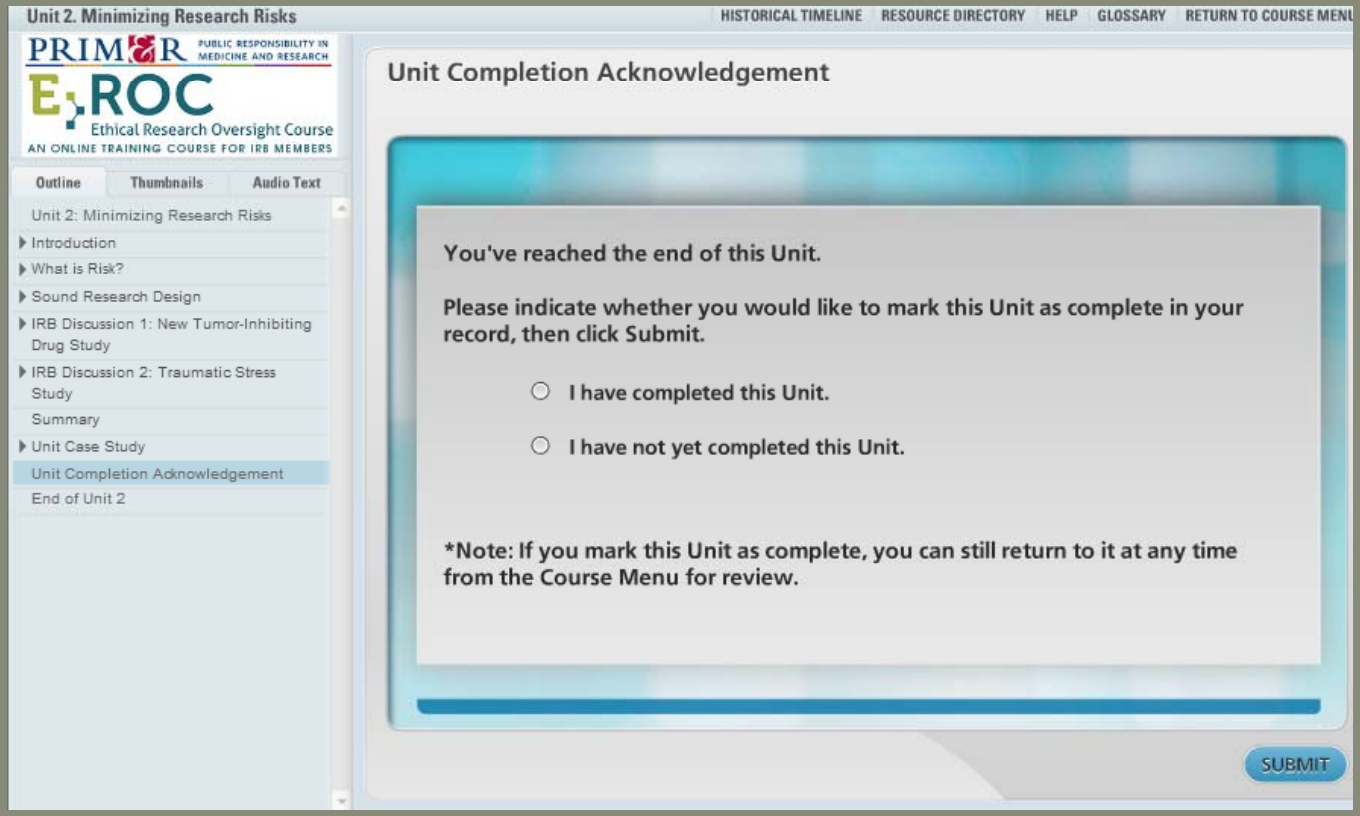
The Resource Directory links to the documents referenced throughout the course.

# Glossary


GLOSSARY
A B C D E F G H I J K L M N O P Q R S T U V W X Y Z
Select a term:
Adverse event
AE
Aneurysm
Anonymous data collection
Autonomous
Behavioral
Beneficence
Biostatistician
Blinding
CBER
CFR
Chemotherapy
Clinical trial
Cognitive
Beneficence
Intending to do right or good by someone, as through treating them with courtesy and respect. Also, aiming to aid or assist an individual in their best interest to ensure their well-being by maximizing possible benefits and minimizing potential harms, in addition to ensuring their rights and welfare. This Belmont principle refers to the ethical obligations in research (1) to do no harm and (2) to maximize possible benefits and minimize possible harms.
Close

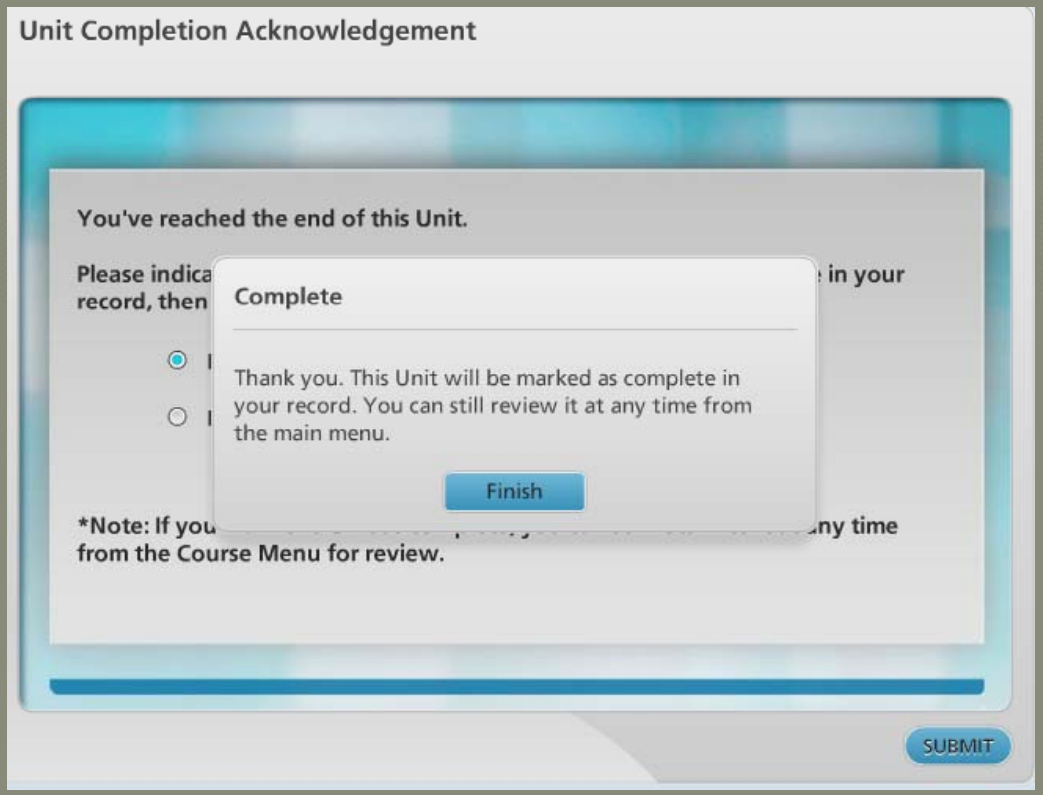
The Glossary defines key terms and acronyms referenced in the course. There is also an audio feature, on the top right hand corner of the glossary window. If you click on it, the narrator reads the definition aloud.

# Unit Completion Feature


Unit 2. Minimizing Research Risks
HISTORICAL TIMELINE
RESOURCE DIRECTORY
HELP
GLOSSARY
RETURN TO COURSE MENU
PRIM&R PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH
E-ROC Ethical Research Oversight Course
AN ONLINE TRAINING COURSE FOR IRB MEMBERS
Outline
Thumbnails
Audio Text
Unit 2: Minimizing Research Risks
Introduction
What is Risk?
Sound Research Design
IRB Discussion 1: New Tumor-Inhibiting Drug Study
IRB Discussion 2: Traumatic Stress Study
Summary
Unit Case Study
Unit Completion Acknowledgement
End of Unit 2
Unit Completion Acknowledgement
You've reached the end of this Unit.
Please indicate whether you would like to mark this Unit as complete in your record, then click Submit.
I have completed this Unit.
I have not yet completed this Unit.
*Note: If you mark this Unit as complete, you can still return to it at any time from the Course Menu for review.
SUBMIT

Once you finish a unit, make sure that you mark it as complete. Select the I have completed this unit option, and then click Submit.

# Unit Completion Acknowledgement


Unit Completion Acknowledgement
You've reached the end of this Unit.
Please indica
record, then
in your
Complete
Thank you. This Unit will be marked as complete in your record. You can still review it at any time from the main menu.
Finish
*Note: If you
ny time
from the Course Menu for review.
SUBMIT

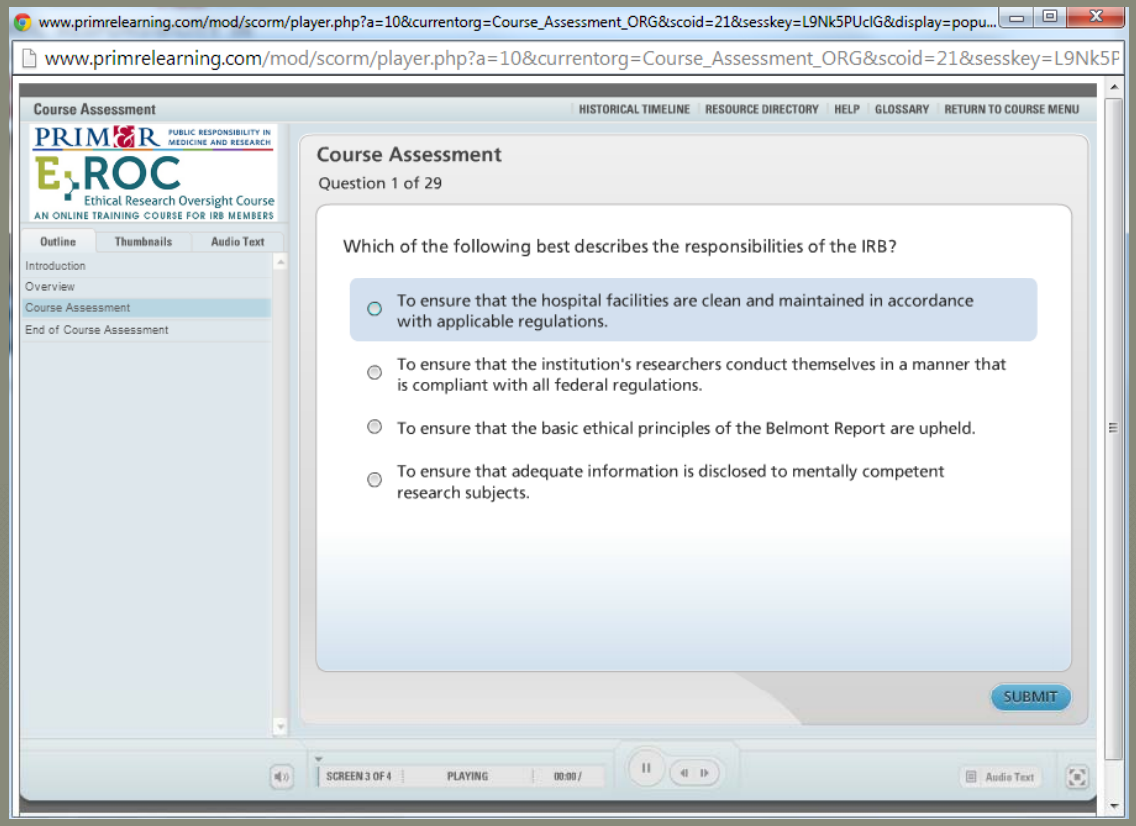
Once you click that you have completed a unit, a Complete box appears. After you click Finish, you can close the unit. You will then be brought back to the course table of contents

# Help

HELP
Unit 1. Welcome to the Institutional Review Board
HISTORICAL TIMELINE
RESOURCE DIRECTORY
GLOSSARY
HELP
RETURN TO COURSE MENU
Introduction
Move your cursor over the red circles and click on them to familiarize yourself with all the navigation and function buttons within this e-learning module.
Click the "x" in the upper right of this pop-up window to close it.
Protection System
Authority of an IRB
IRB Member Roles
Unit Case Study
Unit Completion Acknowledgement
End of Unit 1
E-ROC
Ethical Research Oversight Course
AN ONLINE TRAINING COURSE FOR IRB MEMBERS
Course Introduction
DEVELOPED BY:
PRIM&R
Click NEXT to continue.
SCREEN 1 OF 25
PLAYING
Close

The Help screen offers an overview of how the course works. To explore a feature, just click or hover over the red dot.

# Course Assessment


www.primrelearning.com/mod/scorm/player.php?a=10&currentorg=Course_Assessment_ORG&scoid=21&sesskey=L9Nk5PUclG&display=popu...
www.primrelearning.com/mod/scorm/player.php?a=10&currentorg=Course_Assessment_ORG&scoid=21&sesskey=L9Nk5P
Course Assessment
HISTORICAL TIMELINE
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Course Assessment
Question 1 of 29
Which of the following best describes the responsibilities of the IRB?
To ensure that the hospital facilities are clean and maintained in accordance with applicable regulations.
To ensure that the institution's researchers conduct themselves in a manner that is compliant with all federal regulations.
To ensure that the basic ethical principles of the Belmont Report are upheld.
To ensure that adequate information is disclosed to mentally competent research subjects.
SUBMIT
SCREEN 3 OF 4
PLAYING
00:00 /
Audio Text

In order to receive a certificate of completion, you must take the Course Assessment, and achieve a score of at least 80%.